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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,006

11/17/2003

Daniel Dupret

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10/26/2006

EXAMINER

GUIDRY, GUY L

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WASHINGTON, DC 20006-1109

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,006

Applicant(s)

DUPRET ET AL.

Examiner

Guy Guidry, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-14,16-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 10, 11, 13, 14, 17-19, 22, 23 is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7,9,12,16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a response filed 16 August 2006 to the Office Action mailed 16 May 2006. Claims 2, 4-5, 15, 20 and 24-27 are canceled. Claim 1 has been amended. Claims 1, 3, 6-14, 16-19 and 21-23 are currently pending in this application and under consideration in this Action. All previous objections/rejections not repeated herein are hereby withdrawn. Previous rejections to canceled claims have been rendered moot by Applicant's cancellation of those claims. A response to Applicant's arguments will be set forth, where appropriate, immediately following any statement of rejection repeated herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 7, 9, 12, 16, 21 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tsai-Wu et al. (Analytical Biochemistry, 1999, 275: 127-129).

The rejection is of record. Applicant argues that the instant invention is directed to a method for obtaining polynucleotide fragments for use in polynucleotide shuffling and that the goal of Applicant's invention is to produce a variety of fragments for use in polynucleotide shuffling which not the goal of Tsai-Wu. Applicant argues that the

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reference teaches M13mm3 and M13mm4 because they have identical DNA sequences except for a single nucleotide, which allows the introduction of a G/A mismatch when mixed together. The A and G strands were prepared by PCR using 5' and 3' primers and therefore, the G/A mismatch is purposely introduced, but not through the PCR process.

Applicant also argues that, the Tsai-Wu reference uses KlenTaq DNA polymerase, not Taq polymerase and that KlenTaq polymerase is usually used in a mixture with a proofreading polymerase to provide greater fidelity in order to prevent mutations during the amplification. Applicant also states that even if errors were introduced in the DNA sequences in tile method disclosed in the Tsai-Wu reference, the goal of the study was not to prepare a plurality of polynucleotide fragments, but to intentionally introduce a single G/A mismatch in a DNA sequence.

Applicant further argues that the aim of the reference polyacrylamide gel was to analyze the quality of the mismatch heteroduplex, not to produce fragments for use in polynucleotide shuffling. Moreover, the Tsai-Wu reference does not recover the fragments from the gel.

Response to Applicant's amendments and arguments

Applicant's arguments have been considered and they are not persuasive. The Office notes that the methods disclosed in the Tsai-Wu reference fully meet the limitations of instant claim 1. With respect to intended use of the polynucleotide fragments as found in the preamble of claim 1, if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble

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merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir.1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); *STX LLC. v. Brine*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase "which provides improved playing and handling characteristics" in a claim drawn to a head for a lacrosse stick was not a claim limitation) MPEP 2111.02 II.

With respect to applicants argument that the G/A mismatch is purposefully introduced, the Office notes that obtaining duplexed polynucleotides with mismatches comprises limitations of the instant claims. Further, as previously detailed Tsai-Wu et al. teach M13mm3 and M13mm4 phage, which contain a one base pair mismatch, was used as template for PCR (meeting the limitation claim 1(a) mutagenesis (by PCR per ¶48 of the instant specification, and Taq polymerase is employed, a polymerase known to a person of skill in the art to introduce errors. By Applicant's own admission, the Taq used by Tsai-Wu is prone to produce errors and therefore mixed with a proofreading

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polymerase to increase fidelity and thus, absent evidence to the contrary, the skilled artisan would expect that at least some of the products of the PCR reaction would comprise errors introduced in the DNA sequences in the method disclosed, meeting the limitations of the instant claims.

With respect to Applicant's arguments that, the Tsai-Wu reference does not recover the fragments from their electrophoresis gel, the Office notes that there is no limitation in the instant claims that the generated polynucleotides be recovered or collected.

Therefore, claims 1, 3, 6, 7, 9, 12, 16, 21 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tsai-Wu et al.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Guy Guidry, Ph.D. whose telephone number is 571-272-7928. The examiner can normally be reached on Monday through Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Guy Guidry, Ph.D.

Examiner

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DANIEL M. SULLIVAN
PATENT EXAMINER